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MODEL OF RASAGILINE VERSUS STANDARD OF CARE FOR PARKINSON'S DISEASE: COMPARISON OF PROGRESSION EFFECTS

Johnson S[1], Wang ST[1], Birnbaum H[1], Grubb E[2]
[1]Analysis Group, Inc., Boston, MA, USA, [2]Teva Pharmaceuticals, Kansas City, MO, USA

OBJECTIVES: To incorporate the rasagiline effects observed in the ADAGIO trial into a 25-year Parkinson's Disease (PD) progression model. A model evaluating economic gains from slowing progression was previously developed but progression reduction effects had been hypothetical; including rasagiline effects would be informative. **METHODS:** A disease progression model based on 10 cohort studies containing 3318 patients was used to assess the expected time to progression through Hoehn and Yahr (H&Y) stages one to 5 for those untreated with rasagiline. ADAGIO's relative difference in the Activities of Daily Living-Unified Parkinson's Disease Rating Scale (ADL-UPDRS) from week 0 to 36 for placebo vs. rasagiline (1 mg/day) were used to parameterize the reduction in progression rate for rasagiline. Relative differences in total UPDRS change were also evaluated. Effects observed in the clinical trials were assumed to persist over the course of the model. Medicare claims data for 25,577 patients over 9 years were used to parameterize direct medical costs by H&Y stage. Patients were age 62, 61% male, and 50% H&Y1/50% H&Y2 at baseline. Costs and life-years were discounted at 3%. **RESULTS:** Based on the relative rate of change in ADL-UPDRS, rasagiline reduced progression rates by 76.1%. Rasagiline added $48,226 in drug costs over 25 years. Total direct costs (medical and pharmacy) for untreated patients were $264,389 and $148,736 for rasagiline treated patients; incremental direct costs were $115,653 in favor of rasagiline. Incremental life years gained were 1.97 in favor of rasagiline. At 10 years, the model associated rasagiline with a 45% reduction in patients who were in H&Y3, H&Y4 or H&Y5. Sensitivity analysis indicated that incremental costs varied between $31,146 and $130,888. **CONCLUSIONS:** Clinical trials results for rasagiline (1 mg/day) indicated that the change in relative progression rate versus placebo could yield substantial economic and clinical benefits over a 25 year horizon.

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MOBILITY, INDIRECT COSTS, AND HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS

Coleman CI[1], Roberts MS[2], Sidovar M[3]
[1]University of Connecticut School of Pharmacy, Hartford, CT, USA, [2]University of Connecticut/Hartford Hospital Evidence-based Practice Center, Hartford, CT, USA, [3]Acorda Therapeutics, Inc., Hawthorne, NY, USA

OBJECTIVES: The mobility impairment associated with multiple sclerosis (MS) may have an impact on employment status, work productivity, indirect costs, and health-related quality of life (HRQoL). We estimated indirect costs and HRQoL (utilities) of MS patients in the United States (US). **METHODS:** The North American Committee on Multiple Sclerosis (NARCOMS) registry was used to conduct a cross-sectional study of participants who completed the biannual update and supplemental Spring 2010 surveys. Demographic, employment status, income, mobility impairment, and health utility data were collected from registry participants who agreed to participate in the Mobility Study. Mean annual indirect costs per participant in 2011 USD and mean utilities for the population and for cohorts reporting different levels of mobility impairment were estimated. The Patient Determined Disease Steps, NARCOM's mobility Performance Scale score, and question 1 of the 12-item Multiple Sclerosis Walking Scale were used to define levels of mobility impairment. Indirect costs were estimated using the human capital approach and utilities using the EuroQol 5-Dimension. **RESULTS:** Analyses included 3433 to 3616 participants, depending on survey completeness. Most participants were women (80.1%), ≥40 years of age (80.7%), and had MS for ≥10 years (84.9%). A total of 20.3% of participants experienced a relapse in the past 6 months and 40.4% were receiving a disease-modifying drug; 32% were not working or attending school. Total indirect costs per participant per year were estimated to be $21,680±20,730. The largest relative increases in indirect costs occurred at earlier impairment stages, regardless of the mobility impairment measure used. Participants' mean utility score (0.73±0.18) was lower than that of a similarly aged sample from the general US population (0.87). As with indirect costs, the largest declines in utility were seen at earlier mobility impairment stages. **CONCLUSIONS:** Mobility impairment may contribute to increases in indirect costs and declines in HRQoL in MS patients.

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RESOURCE UTILIZATION AND CAREGIVER BURDEN ASSOCIATED WITH FRAGILE X SYNDROME IN THE UNITED STATES

Bailey D[1], Raspa M[1], Mitra D[1], Sacco P[2]
[1]RTI International, Research Triangle Park, NC, USA, [2]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

OBJECTIVES: To assess the nature and extent of burden experienced by caregivers of patients with Fragile X Syndrome (FXS) in the United States (US). **METHODS:** A total of 351 caregivers enrolled in a FXS survey research registry completed a web-based (93%) or phone-based (7%) survey that captured information on health care utilization, financial burden, employment status, paid and unpaid caregiver hours, and caregiver injuries and mental health. **RESULTS:** Respondents (293 with male child; 58 with female) were mostly female (91%), Caucasian (92%), and married (84%) with an average age of 50 years. Caregivers reported low hospitalization rates (2%) and Emergency Department visits (6%) over the past 12 months. The most commonly seen specialists were ophthalmologists (33%), psychiatrists (33%), developmental-behavioral pediatricians (28%), and neurologists (22%). 40% of males and 22% of females needed at least one of 11 common medical tests/procedures (e.g. CT scan, X-Ray). Nearly 19% of patients needed general anesthesia/sedation for a dental procedure. 66% were on at least one prescription medication for problems related to FXS. On average, parents spent nearly 9 hours/day caring for their child. They also obtained 5 hours of paid support/day. During the past 30 days, the average caregiver and their spouse took 19 hours off from work to care for their child. More than 35% reported that someone in their family had quit working, 28% turned down a job or promotion, 54% changed work hours, and 26% changed jobs. Nearly 29% reported being injured by their child with FXS (16 injuries per year by male children; 4 injuries per year by female children). 35% of caregivers reported seeking treatment for depression or anxiety, and 28% took prescription medications to treat these symptoms. **CONCLUSIONS:** Caring for a child with FXS is associated with substantial caregiver burden and increased health care utilization.

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HEALTH CARE RESOURCE UTILIZATION AND QUALITY OF LIFE IN PATIENTS WITH OVERACTIVE BLADDER DUE TO NEUROGENIC DETRUSOR OVERACTIVITY IN THE UNITED KINGDOM: A DATABASE ANALYSIS

Tang D[1], Colayco D[2], Piercy J[3], Patel V[2], Globe D[2]
[1]The University of Arizona, Tucson, AZ, USA, [2]Allergan, Inc., Irvine, CA, USA, [3]Adelphi Real World, Macclesfield, Cheshire, UK

OBJECTIVES: To evaluate health care resource utilization (HRU) and health-related quality of life (HRQOL) between United Kingdom (UK) Neurogenic Detrusor Overactivity (NDO) patients with and without adequate response to anticholinergics. **METHODS:** A retrospective database analysis was conducted using the Adelphi OAB Disease Specific Programme, a multi-national, cross-sectional survey reported from both patients' and physicians' perspectives. The population for this analysis was limited to UK NDO patients with OAB with or without incontinence, excluding those with stress incontinence. Inadequate response to anticholinergics was defined by switching anticholinergics due to lack of efficacy or tolerability. HRU indicators included: 1) paid employment; 2) OAB-related hospitalization in the past 12 months; 3) ever having undergone OAB-related surgery; and 4) number of physician visits due to their bladder condition in the past three months. HRQOL was measured by the Incontinence Quality of Life Questionnaire (I-QOL) total score. Statistical differences were tested using Fisher's exact test for dichotomous outcomes and Wilcoxon rank-sum test for continuous outcomes. **RESULTS:** The UK sample of patients with OAB or urinary incontinence was 1304 patients recruited by 122 physicians. A total of 40 NDO patients who filled out a self-completion questionnaire were identified, of whom 24 (60%) had inadequate response to anticholinergics. A significantly higher proportion of patients with inadequate response to anticholinergics underwent OAB-related surgeries (N(%): 11(46%) vs. 0(0%), $p<0.01$) versus patients with adequate response. In addition, patients with inadequate response had significantly more physician visits (mean(SD): 3.6(2.7) vs. 1.7(1.6), $p=0.03$) and a statistically and clinically lower I-QOL total score (mean(SD): 49(18) vs. 72(23), $p<0.01$). The proportion of patients on paid employment or have had OAB-related hospitalization did not significantly differ between the groups. **CONCLUSIONS:** Patients with inadequate response to anticholinergics were more likely to have greater health resource utilization and lower quality of life compared with patients with adequate response.

NEUROLOGICAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

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ASSESSING THE RELATIONSHIP BETWEEN THE NUMBER OF NURSING SUPPORT ENCOUNTERS AND MEDICATION POSSESSION RATIO IN RELAPSING REMITTING MULTIPLE SCLEROSIS PATIENTS RECEIVING GLATIRAMER ACETATE

Jones J, Scheidt D, Kaushal R, Carroll CA
Teva Pharmaceuticals, Kansas City, MO, USA

OBJECTIVES: To evaluate the relationship between the numbers of patient encounters over a two year period and medication possession ratio (MPR) in patients receiving services through a voluntary support program sponsored by the manufacturer of Glatiramer Acetate. **METHODS:** De-identified patient records were derived from a decision support system used for normal business operations. Patient records were included in the evaluation if they were 1) continuously enrolled in the program for a minimum of 24 months, and 2) received Glatiramer Acetate. Patients were grouped into four cohorts based upon the average number of encounters with the support services over the two year enrollment period. Chi-squared statistics were used to assess variation in categorical variable and Analysis of Variance (ANOVA) compared mean values for continuous variables. **RESULTS:** A total of 10,989 patients were continuously enrolled in the support program between the dates of September 2002 and August 2011. The mean age of the study population was 45 years with no difference in mean age observed across the four cohorts ($p=0.09$). The mean MPR for the study population was 0.85. Patients utilizing the support services once or twice during the two year study period had a lower MPR (0.84) than patients who utilized the services more frequently (0.87). **CONCLUSIONS:** Data from retail and specialty pharmacy services included within the Invision DataMart™ estimates a MPR for Glatiramer Acetate of 0.76 to 0.80. Nursing support services for multiple sclerosis enhance patient adherence by up to about 15% over that observed through retail or specialty pharmacy services alone. Costs of such service accrue to the sponsor while the benefit of improved compliance (i.e. lower medical expenditures) accrues to payers.

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POTENTIAL HUMANISTIC BENEFITS OF PEGYLATION IN THE TREATMENT OF MULTIPLE SCLEROSIS: A SYSTEMATIC REVIEW OF THE LITERATURE

Becker RV
Russell Becker Consulting, Chicago, IL, USA